PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7: G01S 5/16, 15/89, A61B 17/17, 8/08

A1

(11) International Publication Number:

WO 00/63719

۱ /

(43) International Publication Date:

26 October 2000 (26.10.00)

(21) International Application Number:

PCT/EP99/02634

(22) International Filing Date:

20 April 1999 (20.04.99)

(81) Designated States: AU, CA, JP, NZ, US, ZA, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

(71) Applicant (for all designated States except CA US): SYNTHES AG CHUR [CH/CH]; Grabenstrasse 15, CH-7002 Chur (CH)

(CH)

(71) Applicant (for CA only): SYNTHES (U.S.A.) [US/US]; 1690 Russell Road, P.O. Box 1766, Paoli, PA 19301–1222 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): NOLTE, Lutz, Peter [CH/CH]; Wartbodenstrasse 1 K, CH-3626 Hünibach (CH). SATI, Marwan [CA/CH]; Hausmattrain 44, CH-4600 Olten (CH). MOULDER, Christopher, J. [US/US]; 6200 Wilson Boulevard 322, Falls Church, VA 22044 (US). WENTKOWSKI, Michael [DE/CH]; Bernrainstrasse 5, CH-8556 Wigoltingen (CH). SCHERRER, José, L. [CH/CH]; Bienkenstrasse 3, CH-4702 Oensingen (CH).

(74) Agent: LUSUARDI, Werther; Dr. Lusuardi AG, Kreuzbühlstrasse 8, CH-8008 Zürich (CH).

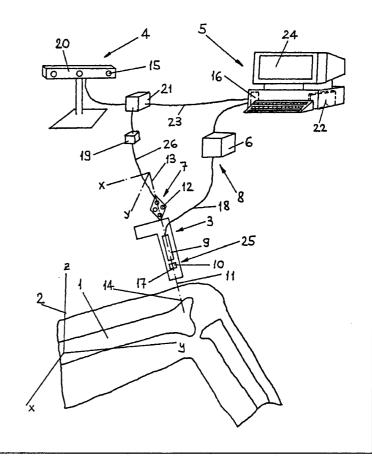
Published

With international search report.

(54) Title: DEVICE FOR THE PERCUTANEOUS OBTAINMENT OF 3D–COORDINATES ON THE SURFACE OF A HUMAN OR ANIMAL ORGAN

(57) Abstract

Device for the percutaneous obtainment of coordinates of points on the surface of a human or animal organ and within a three-dimensional coordinate system (2), comprising A) an ultrasound device (3) with a longitudinal axis (11) and at least three energy emitting or receiving means (7) to be used as markers (12); B) a position measurement device (4) to determine the position of the energy emitting or receiving means (7) with reference to a three-dimensional reference coordinate system (2) in space; and C) at least one computer (5) connected to the ultrasound device (3) and the position measurement device (4), whereby D) the ultrasound device (3) further comprises focusing means (25) to focus the ultrasound beam.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT A	Armenia Austria Australia	FI FR	Finland	LT			
AU A		FR			Lithuania	SK	Slovakia
	Australia		France	LU	Luxembourg	SN	Senegal
AZ A		GA	Gabon	LV	Latvia	SZ	Swaziland
	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA B	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB B	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE B	Belgium	GN	Guinea	MK	The former Yugoslav	TM	Turkmenistan
BF B	Burkina Faso	GR	Greece		Republic of Macedonia	TR	Turkey
BG B	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ B	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR B	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY B	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA C	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF C	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG C	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH S	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI C	Côte d'Ivoire	KP	Democratic People's	NZ	New Zealand		
CM C	Cameroon		Republic of Korea	PL	Poland		
CN C	China	KR	Republic of Korea	PT	Portugal		
CU C	Cuba	KZ	Kazakstan	RO	Romania		
CZ C	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE G	Germany	LI	Liechtenstein	SD	Sudan		
DK D	Denmark	LK	Sri Lanka	SE	Sweden		
EE E	Estonia	LR	Liberia	SG	Singapore		

WO 00/63719 PCT/EP99/02634

1

DEVICE FOR THE PERCUTANEOUS OBTAINMENT OF 3D-COORDINATES ON THE SURFACE OF A HUMAN OR ANIMAL ORGAN

The present invention relates to a device for the percutaneous obtainment of coordinates of points on the surface of a human or animal organ and within a three-dimensional coordinate system as defined in the preamble of claim 1 and a method for the percutaneous obtainment of coordinates of points on the surface of a human or animal organ and within a three-dimensional coordinate system as defined in the preamble of claim 21.

Medical imaging is used extensively in orthopaedics to view the state of musculo-skeletal structures that require correction, repair or replacement. Planar X-ray, X-ray computed tomography (CT) and magnetic resonance imaging (MRI) are image modalities used preoperatively to diagnose and plan surgical interventions. Transfer of this data to the surgical theatre is still mainly intuitive. Computer assisted surgery (CAS), image guided surgery and medical robotics provide a quantitative link between medical imaging using images acquired preoperatively or intraoperatively and surgical actions allowing the surgeon to view, in real time, the orientation of the surgical instruments relative to the

patient. This provides the surgeon with a means to precisely navigate and plan tool movements with respect to normally hidden anatomical structures.

A key issue in computer assisted surgery (CAS) is to establish a relationship between the patient's intraoperative position and the data of the medical images. The process of computing a transformation from coordinates within an on-site coordinate system to image coordinates is referred to as "registration" or "matching".

In the new field of computer assisted surgery (CAS), light-weight "dynamic reference bases" allow the surgeon to freely manipulate the patient according to complex procedures without loosing valuable image generated data. Registration or matching implies obtaining coordinates of points in the medical image reference frame and in the on-site three-dimensional coordinate system in space from the position measurement device. Currently, however, this registration process is invasive requiring the surgeon to have direct access to fiducial markers implanted in the bone or specific, predetermined landmarks on bone surfaces [Nolte] that are digitized with a positioning device. Recent developments allow the surgeon to obtain a number of points of the bone with the positioning device and this "cloud of points" can be mathematically fit onto the medical image (e.g. Computer tomogram CT) of the bone surface through an optimisation algorithm [Gong] [Bächler]. This process is termed "surface matching".

Although "surface matching" has greatly improved the versatility of CAS systems, it requires large incisions or transcutaneous needles that pierce the skin and touch the surface of the bone. Since orthopaedic surgery often involves interactions on bones hidden deep beneath soft tissues, open procedures can imply, both significant risks of infection and long recovery time. There is obvious potential to greatly expand the usefulness of CAS technology if a practical method for minimal invasive registration were developed.

From the US 5,447,154 CINQUIN a method for determining the position of an organ is known. This known invention relates to the field of surgery and more particularly relates to methods and devices for positioning a therapeutic or diagnostic tool as a function of three-dimensional images, that can be preoperation images recorded e.g. with a X-ray computed tomography (CT) scanner or Magnetic Resonance Imaging (MRI) of a patient's organ. For this purpose, this known invention provides the use of a device providing a sparse set of three-dimensional surface points on the organ of interest during surgery. Then, these surface points are registered (matched) with three-dimensional functional image that contains far more detailed information on the organ's surface morphology. To obtain the sparse set of three-dimensional surface points of the organ intra-operatively, the invention provides the use of echography probes. The organ surface is obtained by analysing a reconstructed two-dimensional "image slice" provided by the

WO 00/63719 PCT/EP99/02634

4

ultrasound probe. Both the ultrasound probe and the organ are instrumented with a three-dimensional position tracking device which allows calculation of the identified surface point in 3D space with respect to the patient.

From the WO98/08112 EMMENEGGER ET AL a device for recording ultrasound images is known. The position of these ultrasound images is uniquely defined with respect to any arbitrary three-dimensional coordinate system in space through determining the position and orientation of the ultrasound head. This known device comprises an ultrasound head which can be freely moved by hand, an ultrasound recording apparatus and a three-dimensional position measurement system to determine the position of the ultrasound head. This measurement of the position of the ultrasound head is performed by means of measurement of lengths of at least three points provided through markers affixed to the ultrasound head. The measurement of lengths is realized via interchanging electromagnetic energy between markers attached to the ultrasound head and sensors that are part of the position measurement system and via utilization of interference phenomena of electromagnetic waves and/or via determination of running periods. In one preferred embodiment of this known device the measurement of the position of the ultrasound head is performed by means of a custom position measurement system OPTOTRAK, Northern Digital, Waterloo, On.

The disadvantage of these known methods and the known device is the use of a reconstructed ultrasound image to identify points on the organ's surface intraoperatively. The identification of the organ's surface from a noisy ultrasound-generated image is difficult. Much information on exact anatomy contour is lost in image reconstruction and conversion to a video signal and digitisation of this signal. Ultrasound systems are generally designed to image soft tissues making them sensitive to small changes in acoustic impedances. This produces a considerable amount of "noise" in the constructed image and obscures the surface of the bone. Using the video output of these systems further degrades the signal. The picture must then be manually segmented (i.e. finding the surface of the bone), which requires operator input. Once the picture has been segmented, the surface points can be automatically fitted to the coordinate system of the preoperatively acquired CT image.

The objective of the invention is to provide a device allowing the identification of points on the surface of a human or animal organ within the on-site coordinate system through signal analysis directly on the reflected ultrasound signal effected through a focused one-dimensional ultrasound beam.

The invention solves the above problem by means of a device for the percutaneous obtainment of coordinates of points on the surface of a human or animal organ and within a three-dimensional coordinate system offering the features of claim 1 and a method for the percutaneous obtainment of

coordinates of points on the surface of a human or animal organ and within a three-dimensional coordinate system offering the features of claim 21.

The device is used in a similar fashion to a simple pointing device to obtain either specific anatomical landmarks (for example the spinous process, left and right superior facet joints) to be used for "paired point" matching [Nolte] or for a "cloud of points" on the organ surface to be used for surface matching the medical image to the object [Gong] [Bächler].

The device according to the invention provides the following advantages:

- a) The raw signal analysis of the reflected ultrasound signal effected through the focused one-dimensional ultrasound beam provides more accurate information on anatomical surface location;
- b) The raw signal analysis can be performed in real-time;
- c) The narrow beam width, at desired depth, minimizes detection of "dispersed" signals; and
- d) The signal analysis provides anatomic bone contour position with 0,5 mm axial accuracy and location of the surface point in the 3 D coordinate system with an accuracy of below 1 mm.

The Device for the percutaneous obtainment of coordinates of points on the surface of a bone and within a three-dimensional coordinate system, comprises

7

- A) an ultrasound device sending an ultrasound beam along an axis and at least three non-collinearly arranged markers;
- a position measurement device to determine the position of the markers with reference to a three-dimensional reference coordinate system which may be an on-site coordinate system; and
- C) a computer connected to the ultrasound device and the position measurement device provided with software to evaluate the coordinates from the data received from the ultrasound device and the position measurement device; whereby
- D) the ultrasound device comprises focusing means to focus the ultrasound beam.

The markers are energy emitting, receiving or reflecting means depending on the position measurement device being used. For instance as energy emitting means:

- Light sources;
- Light emitting diodes (LED's);
- Infrared light emitting diodes (IRED's);
- Accoustic transmitters; or
- Coils in order to establish a magnetic field;

or as energy receiving means:

- Photodiodes;
- Microphones; or
- Hall-effect components;

may be installed.

Furthermore, the ultrasound device comprises

a transducer that alternately emits and receives energy by means of ultrasonic waves;

a combined pulser/receiver unit controlled by the computer and has the function of both electrically stimulating the transducer and of receiving and amplifying the echo of the ultrasonic signal received from the transducer; and converter means to convert the amplified analogue signal received from the combined pulser/receiver unit into a digital signal.

The ultrasound device emits and receives energy by means of ultrasonic waves along an axis. The reception of one-dimensional ultrasonic waves requires little signal processing and, hence, greatly increases speed of measurement. The few required components of the ultrasound device facilitate the integration of the device into an existing computer assisted surgery system (CAS).

The point on the surface of the organ, particularly the bone, whose position is desired in coordinates within the three-dimensional coordinate system is defined by the point of intersection of the ultrasound beam axis of the ultrasound device with the surface of the bone. The location of the point within the coordinate system of the ultrasound probe is measured by means of the ultrasound probe and evaluation of the received

signals by means of the computer and the positions of the markers that are measured by means of the position measurement device. The conversion of the coordinates of the point within the coordinate system of the ultrasound probe into coordinates within the on-site coordinate system is performed by means of a coordinate transformation through the computer.

In a further embodiment of the device according to the invention the computer is provided with a high-speed analog to digital converter board (ADC), a fast processor and custom-made signal analysis software in order to obtain real-time data processing.

The transducer is preferably provided with a specific frequency f enabling a desired axial resolution of the ultrasound beam at a desired depth of penetration of the emitted ultrasound waves. The axial resolution is the minimal distance that two distinct echoes can be distinguished from one another in the axial direction. It is dependant of the wavelength 1 of the ultrasound beam whereby the wavelength 1 depends on the frequency f by:

$$1 = c / f$$

wherein c is the average velocity of sound.

Suitable results are achieved for obtaining points on bone surface by using a frequency f of the transducer within the range of 1 MHz to 15 MHz, preferably within the range of 4 MHz to 6 MHz.

Higher frequencies f provide better resolution but are attenuated faster than lower frequencies f in tissue. As a result, the mean frequency penetrating the tissue becomes lower as it travels deeper into the tissue. So, the highest frequency that will penetrate to a given depth is chosen to yield the best axial resolution.

The lateral resolution varies along the depth of the signal but is below 1 mm at the -9 dB point.

The ultrasound beam can be focused within the near field region given by:

$$N = D^2 * f / 4c$$

wherein D is the diameter of the transducer and N is the length of the near field.

With higher frequencies and the larger diameter transducers, the beam can be focused more tightly, yielding better lateral resolution.

In a further preferred embodiment of the device according to the invention the transducer has a diameter of 12,7 mm. The diameter depends on the application. A smaller diameter is suitable for shallower depth.

Moreover, the ultrasound device may be provided with lenses such that the ultrasound beam is more focusable in order to increase signal quality and accuracy. A lens or a set of lenses alow focusing to below 1 mm lateral resolution over a range of 1 to 80 mm. In the preferred embodiment, the lenses consist of two detachable flat surface axicon lenses, focusing the ultrasound beam 5 - 30 mm and 25 - 75 mm with a lateral resolution of 1 mm at - 9 dB. The lenses are attached to the ultrasound device, one at a time, with a screw cap and designed to have an optimal interface with the skin, i.e. allowing maximum energy to be transferred to the tissue.

In another embodiment of the device according to the invention, a 10 MHz ultrasound device is equipped with a "delay line" allowing focusing between 1 mm and 10 mm.

The transducer is electrically driven and the electrical signal caused by the echo is received by a pulser/receiver which is controlled by the computer and may be a custom DPR35-S, Sonix, Inc., Springfield, Va. This pulser/receiver unit is capable of initiating a pulse with an energy emission between 80 μ J and 120 μ , preferably between 95 μ J and 105 μ J and has a maximum gain of approximately 50 dB. The pulser/receiver sends a high voltage pulse with a voltage of between 200 V - 400 V to excite the transducer. This is a sharp pulse with a width less than the resonance frequency of the transducer. The receiver amplifies and filters the signal received from the transducer.

WO 00/63719 PCT/EP99/02634

As converter means, a custom high-speed analog-to-digital conversion board (ADC) e.g. STR*864, Sonix, Inc., Springfield, Va. may be used in order to convert the amplified analogue signal received from the combined pulser/receiver unit into a digital signal.

12

To control the pulser/receiver and the ADC board a custom LabVIEW program is used. This LabView program additionally enables the display of the received ultrasound signal and an alteration of equipment parameters as gain, pulse power and damping to improve the organ detection and distance evaluation.

As computer, a PC using a Pentium 166 with MMX may be used. Such the required signal processing comprising the received signals from the ultrasound device and from the position measurement device may be performed in real-time.

A custom position measurement system e.g. OPTOTRAK 3020 System, Northern Digital, Waterloo, On. may be employed. This OPTOTRAK 3020 System preferably comprises a

- OPTOTRAK 3020 Position Sensor consisting of three one-dimensional charge-coupled devices (CCD) paired with three lens cells and mounted in a stabilized bar. Within each of the three lens cells, light from an infrared marker is directed onto a CCD and measured. All three measurements together determine in real time the 3D location of the marker.
- System Control Unit;
- PC interface card and cables;

PCT/EP99/02634

- Data collection and display software; and
- Strober and marker kit.

When using a CAS application running on a workstation, a client-server architecture may be employed. A PC acts as an ultrasound server and data on distance to the bone is transmitted to the client application through a UDP socket connection to the workstation running position measurement software whenever a request is made.

In a preferred embodiment of the invention the device further comprises a calibration unit. Preferably this calibration unit is constructed of Plexiglas with a hole having the diameter of the ultrasound device. The calibration unit may be cube shaped with the hole drilled in the center such that the distance from the bottom of the hole to the bottom of the calibration unit is in the range of between 20 mm to 30 mm. To calibrate the ultrasound device it is inserted in the calibration unit and echoes are received from the interface of the bottom of the calibration unit and air. These echoes are very large and easy to detect. Since the speed of sound in Plexiglas and the distance travelled are known, the echo can be used to calculate an offset from the ultrasound device head to the interface with the calibration unit. The offset is used in all subsequent distance calculations.

The method for the percutaneous obtainment of coordinates of points on the surface of a human or animal organ and within a three-dimensional coordinate system using the device according to the invention comprises the steps of

- A) precalibration of the ultrasound device that comprises the calibration of the ultrasound device head and its ultrasound beam axis which coincides with the axis of the ultrasound device with respect to a coordinate system fixed with the ultrasound device in order to calculate echo distances and the calibration of the coordinate system fixed with the ultrasound device with respect to the on-site coordinate system in order to calculate the three dimensional position of the point on the surface of the organ where the ultrasound signal is echoed; and
- B) measurement of coordinates of points on the surface of a human or animal organ with respect to a three-dimensional coordinate system performed in real-time by means of raw signal analysis.

In order to enable a real-time measurement the calibration further comprises the use of the received ultrasound signal when the ultrasound device is inserted in the calibration unit in order to establish a signal template. Using this template the raw signal analysis is performed by means of comparison of the received measuring signal with the template for which a cross-correlation algorithm (XCORR) is used.

15

Cross-correlation showed to be a fast and precise method for evaluating the echoes from tissue bone interfaces. In vivo the only meaningful echo is that from the interface between soft tissue and bone. This allows to only search for the minimum cross-correlation, thereby simplifying the algorithm.

Other algorithms to perform the signal comparison would be standard deviation (STDDEV) or short time Fourier transform (STFT).

The calibration of the coordinate system fixed with the ultrasound device with respect to the on-site coordinate system is performable by inserting the ultrasound device firmly into the calibration unit so that both are in view of the position measurement device.

The preferred embodiment of the device according to the invention is elucidated below in relation to the illustratively embodiment partly shown in diagrammatic form.

Fig. 1 shows the preferred embodiment of the device according to the invention in diagrammatic form.

WO 00/63719 PCT/EP99/02634

16

In fig. 1 the device according to one embodiment of the invention is represented. It comprises a three-dimensional position measurement device 4 which is connected to a computer 5 and a manually and freely moveable ultrasound device 3 connected to the computer 5 as well.

The function of the ultrasound device 3 is defined by emitting energy in the form of ultrasonic waves in the direction of the ultrasound beam axis by means of a transducer 9 and receiving the ultrasonic waves reflected on the surface of the bone 1 in the direction of the ultrasound beam axis by means of the transducer 9. The diagram shows the case where the longitudinal axis 11 of the ultrasound device 3 coincides with the ultrasound beam axis. The transducer 9 thereby converts voltage into sound during transmission and sound into voltage during reception. A pulser/receiver 6 (e.g. DPR35-S, Sonix, Inc., Springfield, Va.) which is controlled by the computer 5 is connected to the transducer 9 by means of a coaxial cable 18 and has the function of electrically stimulating the transducer 9 and of receiving and amplifying the voltage signal returned from the transducer 9. The pulser/receiver 6 is capable of initiating a 100 $\,\mu J$ pulse and has a maximum gain of 50 dB. The received signal is sampled at a frequency f > $2 \cdot f_{Nyquist}$ with a high-speed analog-to-digital conversion (ADC) board 16 (e.g. STR*864, Sonix, Inc., Springfield, Va.) connected to the computer 5. To control the pulser/receiver 6 and the ADC board 16 the computer 5 is provided with a custom program. At the computer 5 the received ultrasound signal is displayed at the

display 24 and equipment parameters can be altered to improve bone 1 detection and distance calculation. To focus the emitted ultrasound beam 5-30 mm and 25-75 mm the ultrasound device 3 is provided with lenses 10 which consist of detachable flat surface axicon lenses. Fluid between these lenses 10 and the transducer 9 allow further change in focus depth by using different fluids. For the present invention water is used as a fluid. The lenses 10 may be screwed on one at a time.

By means of the ultrasound device 3 operating with amplitude mode ultrasound (A-mode) or one-dimensional pulse-echo ultrasound as described above the distance from the ultrasound device head 17 to the point 14 on the surface of the bone 1 which is defined by the point of intersection between the ultrasound beam axis and the surface of the bone 1 in the direction of the ultrasound beam axis is obtained as a result.

The positions of the markers 12 attached to the ultrasound device 3 with respect to the on-site coordinate system 2 are determined by means of the position measurement device 4 (e.g. OPTOTRAK 3020, Northern Digital, Waterloo, Ont.). This position measurement device 4 comprises a position sensor 20 with three optoelectrical cameras 15, a system control unit 21, a computer interface card 22 and cables 23;26 as well as real time 3D data viewing software for viewing the collected data in numeric or graphic form during collection at the display 24 of the computer 5.

To convert the above mentioned distance between the ultrasound device head 17 and the point 14 on the surface of the bone 1 into coordinates within the on-site three-dimensional coordinate system 2 the position of the ultrasound device head 17 and the direction of the longitudinal axis 11 has to be determined within the on-site three-dimensional coordinate system 2. Therefore, the ultrasound device 3 is provided with four infrared light emitting diodes (LED) arranged non-collinearly and serving as markers 12. By means of these four markers 12 a three-dimensional coordinate system 13 fixed with the ultrasound device 3 may be established. To determine the position of the ultrasound device head 17 and the orientation of the ultrasound beam axis with respect to the coordinate system 13 of the ultrasound device 3 a calibration is to be performed. The received calibration data contains information regarding the coordinates of the longitudinal axis 11 coinciding with the ultrasound beam axis and the ultrasound device head 17 with respect to the coordinate system 13, which is stored in a electrically erasable programmable read-only memory 19 (EEPROM) attached at the ultrasound device 3.

Once the position of the markers 12 is determined with respect to the on-site coordinate system 2 the distance between the ultrasound device head 17 and the point 14 on the surface of the bone 1 expressed in coordinates within the coordinate system WO 00/63719

of the ultrasound device 3 can be converted into coordinates within the on-site coordinate system 2 by means of coordinate transformation which can be performed via the computer 5.

Instead of employing a client-server architecture including the computer 5 controlling the ultrasound device 3 and a workstation running the position measurement software and possibly a CAS application as well a single computer comprising the necessary hardware and software may be used to operate the ultrasound device, the position measurement device and possibly a CAS application.

References:

Nolte, L.-P. et al.

Clinical evaluation of a system for precision enhancement in spine surgery

Clinical Biomechanics, Vol. 10, No. 6, pp. 293-303, 1995

Gong, J., Bächler, R., Sati, M., Nolte, L.-P.

Restricted surface matching: A new approach to registration in computer assisted surgery

Proc. 3rd Int.Symp.Med.Robot Comput.Assist.Surg. (MRCAS) 597-605, 1997.

Bächler, R., Bunke, H., Nolte, L.-P.

Restricted Surface Matching - Numerical Optimization and Technical Evaluation

Comput.Aided Surg. 1999

WO 00/63719 PCT/EP99/02634

20

CLAIMS

- 1. Device for the percutaneous obtainment of coordinates of points on the surface of a human or animal organ and within a three-dimensional coordinate system (2), comprising
- A) an ultrasound device (3) with an axis (11) coinciding with the ultrasound beam axis and at least three energy emitting, receiving or reflecting means (7) to be used as markers (12);
- B) a position measurement device (4) to determine the position of the markers (12) with reference to a three-dimensional reference coordinate system (2) in space; and
- C) at least one computer (5) connected to the ultrasound device(3) and the position measurement device (4),characterized in that
- D) the ultrasound device (3) further comprises focusing means (25) to focus the ultrasound beam.
- 2. Device according to claim 1, characterized in that the focusing means (25) comprise at least one lens (10) such that the ultrasound beam is highly focusable in order to increase signal quality and accuracy.
- 3. Device according to claim 2, characterized in that the lenses (10) consist of detachable fluid filled lenses (10).
- 4. Device according to claim 3, characterized in that the lenses (10) consist of detachable water filled lenses (10).

- 5. Device according to one of the claims 2 to 4, characterized in that the lenses (10) are detachable flat lenses.
- 6. Device according one of the claims 2 to 5, characterized in that the ultrasound beam is focussable to 1 mm lateral resolution over a range from 1 mm to 80 mm depth.
- 7. Device according to one of the claims 1 to 6, characterized in that the ultrasound device (3) further comprises a transducer (9) that alternately emits and receives energy by means of ultrasonic waves.
- 8. Device according to one of the claims 1 to 7, characterized in that the ultrasound device (3) further comprises a combined pulser/receiver unit (6) controlled by the computer (5) and having the function of both electrically stimulating the transducer (9) and of receiving and amplifying the echo of the ultrasonic waves received from the transducer (9).
- 9. Device according to one of the claims 1 to 8, characterized in that the ultrasound device (3) further comprises converter means (8) to convert the amplified analogue signal received from the combined pulser/receiver unit (6) into a digital signal.
- 10. Device according to one of the claims 1 to 9, characterized in that the ultrasound device (3) emits and receives energy by means of ultrasonic waves outgoing and returning along the direction of the axis (11).

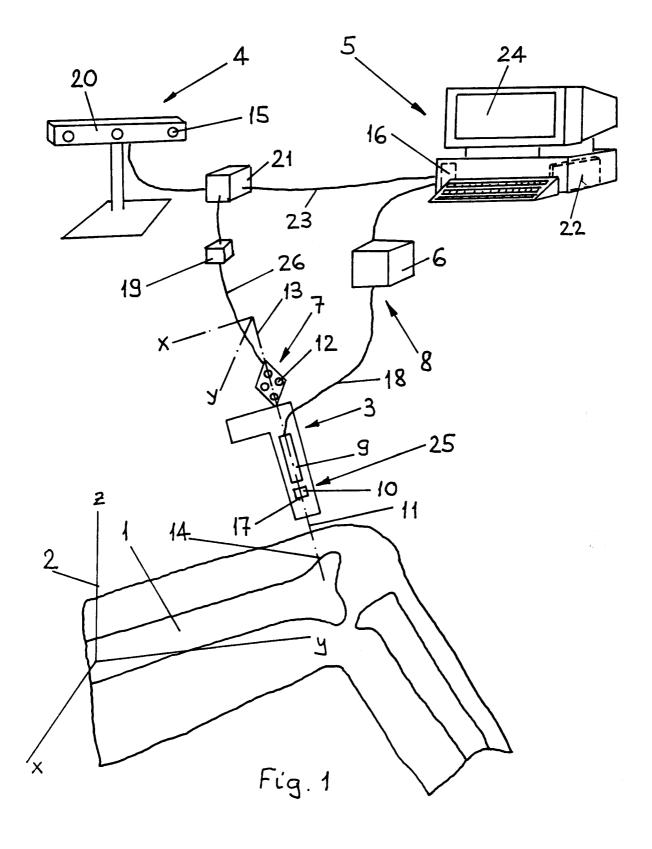
- 11. Device according to one of the claims 1 to 10, characterized in that the computer (5) performs signal processing comprising the received signals from the ultrasound device (3) and from the position measurement device (4) in real-time.
- 12. Device according to claim 11, characterized in that the computer (5) is provided with a high-speed analog to digital (ADC) board (16) in order to obtain real-time data processing.
- 13. Device according to claim 11 or 12, characterized in that the computer (5) is provided with a sufficiently fast central processing unit (CPU) in order to obtain real-time data processing.
- 14. Device according to one of the claims 7 to 13, characterized in that the transducer (9) provides a specific frequency enabling a desired axial resolution of the ultrasound beam at a desired depth of penetration of the emitted ultrasound waves.
- 15. Device according to claim 14, characterized in that the transducer (9) provides a frequency within the range of 1 MHz to 15 MHz.
- 16. Device according to one of the claims 8 to 15, characterized in that the pulser/receiver unit (6) initiates a pulse with an energy emission amounting between 80 and 120 μ J.

- 17. Device according to one of the claims 1 to 16, characterized in that it further comprises a calibration unit.
- 18. Device according to claim 17, characterized in that the calibration unit is constructed of Plexiglas with a hole having the diameter of the ultrasound device (3).
- 19. Device according to claim 17 or 18, characterized in that the calibration unit is cube shaped with the hole drilled in the center.
- 20. Device according to one of the claims 17 to 19, characterized in that the distance from the bottom of the hole to the bottom of the calibration unit is in the range of between 20 mm to 30 mm.
- 21. Method for the percutaneous obtainment of coordinates of points on the surface of a human or animal organ and within a three-dimensional coordinate system (2) using the device according to one of the claims 1 to 20,
- characterized in that the method comprises the steps of
- A) precalibration of the ultrasound device (3);
- B) measurement of coordinates of points on the surface of an organ of a human being or an animal with respect to a three-dimensional coordinate system (2).

- 22. Method according to claim 21, characterized in that the precalibration comprises the calibration of the ultrasound device head (17) and its longitudinal axis (11) with respect to a coordinate system (13) fixed with the ultrasound device (3) in order to calculate echo distances.
- 23. Method according to claim 22, characterized in that the precalibration further comprises the calibration of the coordinate system (13) with respect to the coordinate system (2) in order to calculate the three dimensional position of the point (14) on the surface of the organ where the ultrasound signal is echoed.
- 24. Method according to one of the claims 21 to 23, characterized in that the precalibration further comprises the use of the received ultrasound signal of the ultrasound device (3) inserted in the calibration unit in order to establish a reflected signal template.
- 25. Method according to one of the claims 21 to 24, characterized in that the measurement of the coordinates is performed in real-time by means of raw signal analysis.
- 26. Method according to claim 25, characterized in that the raw signal analysis comprises the comparison of the received measuring signal with the template.

PCT/EP99/02634

27. Method according to claim 26, characterized in that the comparison is performed by means of a cross-correlation algorithm (XCORR).



INTERNATIONAL SEARCH REPORT

Interi nal Application No PCT/EP 99/02634

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 G01S5/16 G01S15/89 A61B17/17 A61B8/08

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

 $\begin{array}{ccc} \mbox{Minimum documentation searched} & \mbox{(classification system followed by classification symbols)} \\ \mbox{IPC 7} & \mbox{G01S} & \mbox{A61B} \\ \end{array}$

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

ENTS CONSIDERED TO BE RELEVANT	
Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
WO 98 08112 A (ENGFER OLAF ;SYNTHES AG (CH); EMMENEGGER NIKLAUS (CH); SYNTHES USA) 26 February 1998 (1998-02-26)	1-5,7, 10,11,14
abstract; figures 1-3 page 12, line 19 -page 15, line 7	21
WO 82 04157 A (BATTELLE INSTITUT E V ;LIERKE ERNST GUENTER (DE); SUDHOF HELMUT (D) 25 November 1982 (1982-11-25)	1-5,7, 10,11,14
abstract; figure 1 page 4, line 10 - line 35 page 5, line 17 - line 28	21
-/	
	WO 98 08112 A (ENGFER OLAF; SYNTHES AG (CH); EMMENEGGER NIKLAUS (CH); SYNTHES USA) 26 February 1998 (1998-02-26) cited in the application abstract; figures 1-3 page 12, line 19 -page 15, line 7 WO 82 04157 A (BATTELLE INSTITUT E V; LIERKE ERNST GUENTER (DE); SUDHOF HELMUT (D) 25 November 1982 (1982-11-25) abstract; figure 1 page 4, line 10 - line 35 page 5, line 17 - line 28

X Further documents are listed in the continuation of box C.	Patent family members are listed in annex.
 Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filling date but later than the priority date claimed 	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family
Date of the actual completion of the international search 20 December 1999	Date of mailing of the international search report 11/01/2000
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo ni, Fax: (+31-70) 340-3016	Authorized officer Niemeijer, R

1

INTERNATIONAL SEARCH REPORT

Inter anal Application No
PCT/EP 99/02634

C.(Continu	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	NOLTE L -P ET AL: "Clinical evaluation of a system for precision enhancement in spine surgery", CLINICAL BIOMECHANICS,GB,BUTTERWORTH SCIENTIFIC LTD, GUILDFORD, VOL. 10, NR. 6, PAGE(S) 293-303 XP004040317 ISSN: 0268-0033 cited in the application	1,21
Α	DE 44 12 073 A (MOELLER J D OPTIK) 12 October 1995 (1995-10-12) column 5, line 14 - line 46; figure 1	1,21
Α	US 4 896 673 A (ROSE FREEMAN H ET AL) 30 January 1990 (1990-01-30) abstract; figures 1,5 column 3, line 47 -column 4, line 35	1,21

INTERNATIONAL SEARCH REPORT

information on patent family members

Interr nal Application No PCT/EP 99/02634

Patent document cited in search report	:	Publication date	Patent family member(s)	Publication date
WO 9808112	A	26-02-1998	AU 3845397 EP 0920642	
WO 8204157	A	25-11-1982	DE 3120611 DE 3142639 EP 0079351	A 05-05-1983
DE 4412073	A	12-10-1995	FR 2718342 GB 2288249 IT T0950277	A,B 11-10-1995
US 4896673	Α	30-01-1990	NONE	